

**\*NOT FOR PUBLICATION\***

**UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY**

JODY JOHNSON and MICHAEL  
JOHNSON,

Plaintiffs,

v.

ETHICON, INC. and JOHNSON &  
JOHNSON,

Defendants.

Civ. Action No. 21-13404 (FLW)

**OPINION**

**WOLFSON, Chief Judge:**

Plaintiffs Jody and Michael Johnson (“Plaintiffs”) brought this action against defendants Ethicon, Inc., and Johnson & Johnson (“Defendants”) in connection with injuries Mrs. Johnson allegedly sustained from a pelvic mesh surgical product that Defendants manufacture. Defendants move to dismiss Plaintiffs’ First Amended Complaint for failure to state a claim, and in lieu of an opposition brief, Plaintiffs cross-move for leave to file a Second Amended Complaint (“SAC”). The proposed SAC asserts claims for negligence, failure to warn, design defect, and loss of consortium, and the Court will consider the proposed SAC as the operative complaint for purposes of the present motions. Defendants oppose the motion to amend on grounds that the amendment would be futile. For the reasons set forth herein, Defendants’ Motion to Dismiss the First Amended Complaint is **DENIED** as moot, and Plaintiffs’ Motion for Leave to Amend is **GRANTED** in part and **DENIED** in part. Consistent with this Opinion, Plaintiffs may file an SAC that asserts strict liability claims for design defect and failure warn, as well as a claim for loss of consortium. The negligence claim is

dismissed. Because the Court concludes that the proposed SAC states a claim for design defect only with respect to certain alleged defects, Plaintiffs are also given leave to amend their design defect claim, consistent with this Opinion, in order to replead their allegations concerning the defects for which the proposed SAC fails to state a claim. Plaintiffs must file their amended complaint within twenty-one (21) days of the date of the accompanying Order.

## **I. BACKGROUND AND PROCEDURAL HISTORY**

The Court draws the facts recited below from Plaintiffs’ proposed SAC and assumes the facts therein are true for purposes of this motion.

Ethicon manufactures the Tension-free Vaginal Tape-Obturator (“TVT-O”) sling, a polypropylene mesh product that is surgically implanted in the pelvic region to treat stress urinary incontinence (“SUI”). SAC ¶¶ 26, 35.<sup>1</sup> SUI is the involuntary loss of urine during movement that places pressure on the bladder. *Id.* ¶ 14. The TVT-O uses Ethicon’s Prolene Mesh, which derives from mesh Ethicon originally designed to treat hernias. *Id.* ¶¶ 20, 26. Ethicon introduced the TVT-O pursuant to the premarket notification process under Section 510(k) of the Federal Food, Drug and Cosmetic Act (FDCA) as a device that is “substantially equivalent” to a device that the Food and Drug Administration (FDA) had already approved. *Id.* ¶¶ 21–25.

Surgeons implant the TVT-O using a transobturator procedure, in which the sling passes through an area of the pelvis called the obturator membrane. *Id.* ¶ 35. Plaintiffs allege that this surgical procedure may cause injuries, including “groin and leg pain,” “numbness and shooting

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<sup>1</sup> The Court takes judicial notice of the fact that the TVT-O is a type of mid-urethral mesh sling, which surgeons implant beneath the urethra to provide support. *See Stress Urinary Incontinence (SUI)*, U.S. Food and Drug Admin. (current as of Apr. 16, 2019), <https://www.fda.gov/medical-devices/urogynecologic-surgical-mesh-implants/stress-urinary-incontinence-sui> (last visited May 25, 2022); *see also Bond v. Johnson & Johnson*, Civ. Nos. 21-05327 and 21-05333, 2021 WL 6050178, at \*9 n.8 (D.N.J. Dec. 21, 2021) (citing *Pension Ben. Guar. Corp. v. White Consol. Indus., Inc.*, 998 F.2d 1192, 1196–97 (3d Cir 1993)) (taking judicial notice of similar FDA document).

pains down the legs,” and “the inability to sit or stand for long periods of time.” *Id.* Plaintiffs also allege that “medical literature . . . associates obturator slings, such as the TVT-O, with a higher rate of dyspareunia [(pain during sexual intercourse)] and vaginal pain” than devices using a retropubic surgical procedure, in which the sling does not pass through the obturator membrane. *See id.*

Plaintiffs allege that certain publications and guidelines recommend against using the TVT-O. In particular, the United Kingdom’s National Institute for Healthcare and Excellence (“NICE”) recommends that “the TVT-O should only be used in exceptional circumstances, if at all.” *Id.* ¶ 52. Plaintiffs also allege that a Joint Position Statement on the Management of Mesh-Related Complications for the FPMRS Specialist (“Joint Position Statement”), which the American Urogynecologic Society (“AUGS”) and International Urogynecological Association (“IUGA”) published jointly in 2020, removed its previous description of “full-length midurethral slings”—using either the transobturator or retropubic procedure—as the “gold standard” for the treatment of SUI. *Id.* ¶¶ 53–54. It now states that “midurethral slings ‘continue to be considered a standard of care for treatment of SUI.’” *Id.* ¶ 54. The Joint Position Statement also allegedly recognizes that transobturator devices such as the TVT-O may cause “extrapelvic pain,” including “groin pain and nerve impingement/entrapment.” *Id.* Similarly, a July 2020 report from the Independent Medicines & Medical Devices Safety Review (“IMMDSR”) notes that the TVT-O is “associated with serious adverse events such as nerve damage, leg pain and mobility issues.” *Id.* ¶ 51.

Plaintiffs allege that Ethicon has marketed the TVT-O as a device that is safe and effective in treating SUI even though, according to Plaintiffs, the TVT-O has high rates of complications, fails to perform as intended, often requires “debilitating re-operations,” and has “caused severe and irreversible injuries.” *Id.* ¶¶ 40–42. Plaintiffs further allege that Ethicon has failed to perform adequate testing and has known that its disclosures to the FDA regarding the TVT-O are misleading.

*See id.* ¶¶ 43–45. And Plaintiffs allege that “[f]easible and suitable” alternative designs compared to the TVT-O were available to Ethicon. *Id.* ¶ 47.

According to the proposed SAC, at some point before September 2010, a surgeon implanted a graft in Mrs. Johnson’s pelvic region to treat an unspecified condition. *See id.* ¶ 34. In or around September 2010, Mrs. Johnson was diagnosed with SUI, perineal scar pain, posterior graft retraction, and dyspareunia, which entails pain during sexual intercourse. *Id.* ¶ 33. Mrs. Johnson then underwent surgery to treat her conditions on September 29, 2010, at the Summit Healthcare Regional Medical Center in Show Low, Arizona. *Id.* ¶¶ 32, 34. Mrs. Johnson’s surgeon, Dr. Patrick Connelly, performed a perineorrhaphy and a graft revision, and he implanted a TVT-O sling to treat her SUI. *Id.* ¶ 34.

Following her 2010 surgery, the pain around Mrs. Johnson’s perineal scar and the TVT-O worsened. *Id.* ¶ 36. On May 2, 2014, Dr. Connelly performed a procedure intended to remove the scar tissue that had formed around the TVT-O in order to relieve Mrs. Johnson’s pain. *Id.* But the “scarring,” “nerve pain” and “vaginal pain” increased after the 2014 surgery, *id.* ¶ 37, and Mrs. Johnson ultimately underwent surgery again on July 27, 2020, in Arizona. *Id.* ¶ 38. Plaintiffs describe the 2020 procedure as “revision surgery of the . . . TVT-O.” *See id.*<sup>2</sup> They allege that the TVT-O caused Mrs. Johnson to “experience[] significant mental and physical pain,” permanent injuries, and economic losses.” *Id.* ¶ 39.

On July 7, 2021, Plaintiffs filed a Complaint asserting violations of the New Jersey Product Liability Act (“NJPLA”), N.J.S.A. 2A:58C-1 *et seq.*, and the New Jersey Consumer Fraud Act (“NJCFA”), N.J.S.A. 56:8-1 *et seq.* ECF No. 1. Plaintiffs then filed their First Amended Complaint,

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<sup>2</sup> Plaintiffs state in their Reply brief that a surgeon removed Mrs. Johnson’s TVT-O device during the revision surgery. *See* ECF No. 17 at 7.

in which they maintained their NJCFA count, asserted two separate counts for design defect and manufacturing defect under the NJPLA, and added a negligence count. ECF No. 4. Defendants move to dismiss all four counts for failure to state a claim. ECF No. 7.

In lieu of an opposition, Plaintiffs filed a Motion for Leave to File a Second Amended Complaint, which asserts four counts: negligence (Count One); strict liability for failure to warn (Count Two); strict liability for design defect (Count Three); and loss of consortium (Count Four). SAC ¶¶ 63–95. The proposed SAC also seeks punitive damages. *See id.* ¶¶ 96–100. Plaintiffs allege that the TVT-O was defective in violation of the laws of New Jersey and Arizona, their home state. *See id.* ¶ 62. Defendants oppose the motion for leave to amend, arguing that amendment would be futile because the proposed SAC fails to state a claim, ECF No. 16, and Plaintiffs filed a Reply, ECF No. 17. Based on their briefs, the parties agree that Arizona law governs Plaintiffs’ substantive claims. *See* ECF No. 16 at 9–10; ECF No. 17 at 6.

## II. LEGAL STANDARD

After a plaintiff amends her complaint once as of right, as occurred here, the plaintiff may move to amend “only with the opposing party’s written consent or the court’s leave.” Fed. R. Civ. P. 15(a)(2). “The court should freely give leave when justice so requires.” *Id.* However, the court may deny a motion to amend when, *inter alia*, amendment would be futile. *Bell v. United Auto Group, Inc.*, Civ. No. 05-2262, 2006 WL 231572, at \*4 (D.N.J. Jan. 30, 2006) (citing *Foman v. Davis*, 371 U.S. 178, 182 (1962)). Defendants contest Plaintiffs’ motion to amend only on grounds that the amendment would be futile.

“In assessing the ‘futility’ of an amendment, the Court ‘applies the same standard of legal sufficiency as applies under Rule 12(b)(6).’” *MedPointe Healthcare Inc. v. Hi-Tech Pharmacal Co.*, 380 F. Supp. 2d 457, 462 (D.N.J. 2005) (quoting *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1434 (3d Cir. 1997)). On a motion to dismiss for failure to state a claim, “courts accept all

factual allegations as true, construe the complaint in the light most favorable to the plaintiff, and determine whether, under any reasonable reading of the complaint, the plaintiff may be entitled to relief.” *Fowler v. UPMC Shadyside*, 578 F.3d 203, 210 (3d Cir. 2009) (quotations and citations omitted). While Rule 8(a) does not require that a complaint contain detailed factual allegations, “a plaintiff’s obligation to provide the ‘grounds’ of [her] ‘entitle[ment] to relief’ requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do.” *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (citation omitted). Thus, to survive a Rule 12(b)(6) motion to dismiss, the complaint must contain sufficient factual allegations to raise a plaintiff’s right to relief above the speculative level, so that a claim “is plausible on its face.” *Id.* at 570; *Phillips v. Cty. of Allegheny*, 515 F.3d 224, 231 (3d Cir. 2008). “A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009).

To determine whether a plaintiff has met the facial plausibility standard under *Twombly* and *Iqbal*, courts within this Circuit apply a three-step test. *Santiago v. Warminster Twp.*, 629 F.3d 121, 130 (3d Cir. 2010). First, the court must “outline the elements a plaintiff must plead to state a claim for relief.” *Bistran v. Levi*, 696 F.3d 352, 365 (3d Cir. 2012). Next, the court “peel[s] away those allegations that are no more than conclusions and thus not entitled to the assumption of truth.” *Id.* Finally, where “there are well-pleaded factual allegations, the court should assume their veracity and then determine whether they plausibly give rise to an entitlement to relief.” *Iqbal*, 556 U.S. at 679.

### III. DISCUSSION

Defendants contend that amendment would be futile because the proposed SAC fails to state a claim for design defect, failure to warn, negligence, and loss of consortium. For the reasons set forth herein, I find that the proposed SAC states strict liability claims for design defect and failure to warn, albeit only with respect to certain alleged defects and omitted warnings. However, because the

strict liability design defect and failure to warn claims subsume the negligence claim, that claim is dismissed. Finally, because Defendants move to dismiss the loss of consortium claim only on grounds that Plaintiffs fail to state an underlying products liability claim, and Plaintiffs have stated a claim for design defect and failure to warn, the loss of consortium claim survives.

#### **A. Strict Liability: Design Defect**

To state a claim for design defect under Arizona law, the plaintiff must plausibly allege that (1) the product in question was “defective,” (2) the defect made the product “unreasonably dangerous,” and (3) the defect “proximately caused” the plaintiff’s injuries. *Turner v. Machine Ice Co.*, 674 P.2d 883, 886 (Ariz. Ct. App. 1983) (citing *Rogers v. Unimac Co.*, 115 Ariz. 304, 307 (1977)). In determining whether a defect renders the product “unreasonable dangerous,” the court must conduct a “risk/benefit” analysis based on the following factors:

(1) The usefulness and desirability of the product; (2) the availability of other and safer products to meet the same need; (3) the likelihood of injury and its probable seriousness; (4) the obviousness of the danger; (5) common knowledge and normal public expectation of the danger (particularly for established products); (6) the avoidability of injury by care in use of the product (including the effect of instructions or warnings); and (7) the ability to eliminate the danger without seriously impairing the usefulness of the product or making it unduly expensive.

*Turner*, 674 P.2d at 886 (quoting *Byrns v. Riddell, Inc.*, 113 Ariz. 264, 267 (1976)).

The proposed SAC lists purported defects associated with the TVT-O, and it generally alleges that the TVT-O caused the injuries Mrs. Johnson experienced. *See* SAC ¶¶ 35, 42, 68, 70–71, 77, 82. In particular, Plaintiffs allege that Mrs. Johnson experienced “scarring,” “nerve pain,” and “vaginal pain” after Dr. Connelly implanted the TVT-O. *See* SAC ¶¶ 36–37; *see also id.* ¶ 71 (alleging Mrs. Johnson suffered “debilitating neuromas”). Defendants contend that Plaintiffs have not plausibly alleged proximate cause because they fail to “connect [Mrs.] Johnson’s injuries to any specific design defect(s)” or explain how certain identified defects tend to cause the injuries that are allegedly associated with those defects. *See* ECF No. 16 at 11–13. Because Plaintiffs must plausibly allege that

the *defects* proximately caused *Mrs. Johnson's* injuries, the Court will review each alleged defect to determine whether Plaintiffs have stated a claim. *See Baca v. Johnson & Johnson*, Civ. No. 20-01036, 2020 WL 6450294, at \*4 (D. Ariz. Nov. 2, 2020) (dismissing design defect claim in pelvic mesh case because the complaint's allegations "simply fail to show how the Product caused *this* Plaintiff's specific injury") (emphasis in original); *Bellew v. Ethicon, Inc.*, Civ. No. 13-22473, 2014 WL 6610685, at \*4 (S.D. W. Va. Nov. 20, 2014) (citing *Jimenez v. Sears, Roebuck & Co.*, 183 Ariz. 399, 402 (1995)) (applying Arizona law and denying plaintiff's motion for summary judgment where plaintiff failed to establish that purported *defects* in a pelvic mesh product proximately caused her injuries). Plaintiffs plausibly allege proximate cause with respect to five asserted defects, but they fail to adequately allege proximate cause as to the remaining defects for one or both reasons Defendants identify.

First, Plaintiffs plausibly allege that the injuries Mrs. Johnson sustained were proximately caused by: 1) the transobturator procedure used to implant the TVT-O; 2) the "propensity" of the TVT-O to "contract or shrink" following implantation; 3) the tendency of the mesh to degrade and fragment; 4) the "pore size and stiffness" of the mesh used in the TVT-O, and 5) the "inelasticity" of the mesh, SAC ¶¶ 35, 68(c), (e), (f), (h), (n). In that connection, Plaintiffs allege that certain medical literature associates transobturator devices with higher rates of vaginal pain and dyspareunia compared to devices that are implanted using a retropubic procedure, and they cite to articles supporting the conclusion that transobturator devices may cause nerve entrapment, damage, and pain. *See id.* ¶¶ 35, 51, 54. Plaintiffs also allege that the mesh used in the TVT-O tends to "contract or shrink," which "causes surrounding tissue to [become] inflamed," leading to painful scarring around the site of implantation, *see id.* ¶ 68(c); that the mesh tends to degrade, fragment, fray, and curl, leading to chronic inflammation and a "fibrotic reaction," *see id.* ¶¶ 68(f), (h), which is a type of scarring; that the "pore size and stiffness" of the TVT-O "created an unacceptable risk of . . . the

mesh ripping through vaginal tissue,” causing “chronic pain,” *id.* ¶ 68(n); and that the “inelasticity” of the mesh prevents the TVT-O from properly “mat[ing] to the delicate and sensitive areas of the pelvis,” which “caus[es] pain upon normal daily activities that involve movement in the pelvis,” including “intercourse.” *Id.* ¶ 68(e). These allegations sufficiently connect the asserted defects, identified above, to the specific injuries—“vaginal pain,” “nerve pain,” “debilitating neuromas,” and “scarring” around the TVT-O—Mrs. Johnson experienced following her implantation surgery. *Id.* ¶¶ 36–37, 71.

The allegations also adequately explain how the foregoing purported defects could have caused Mrs. Johnson’s injuries. *Cf. Moore v. C.R. Bard, Inc.*, 217 F. Supp. 3d 990, 995 (E.D. Tenn. 2016) (dismissing design defect claim in part because the plaintiff failed to adequately “allege *how* the alleged defect(s) caused his injuries”) (emphasis in original) (quotations omitted); *Bond*, 2021 WL 6050178, at \*9 (same). For example, there is a reasonable inference that mesh contraction could inflame the surrounding tissue, leading to the type of scarring Mrs. Johnson experienced. This type of explanation “nudge[s] [Plaintiffs’] claims across the line from conceivable to plausible.” *Twombly*, 550 U.S. at 570. Accordingly, the proposed SAC states a plausible design defect claim based on the foregoing asserted defects.

On the other hand, Plaintiffs’ allegations pertaining to 1) the use of polypropylene mesh, 2) inserting the TVT-O through an area of the body with high levels of bacteria, 3) the propensity of the TVT-O to “creep” or “elongate,” and 4) the use of “non-medical grade material,” *see* SAC ¶¶ 69(a), (b), (d), (k), (m), fail because there are no allegations that Mrs. Johnson experienced the injuries these defects tend to cause. *See Baca*, 2020 WL 6450294, at \*4 (concluding plaintiffs must plausibly allege that a particular defect caused “[the] [p]laintiff’s specific injur[ies]”). Plaintiffs allege that “emerging scientific evidence suggests” polypropylene mesh “is biologically incompatible with human tissue and promotes an immune response in a large subset of the population,” which causes “degradation

of the pelvic tissue” and can lead to “severe adverse reactions.” SAC ¶¶ 68(a), 70. But Plaintiffs do not allege that Mrs. Johnson experienced an immune response or pelvic tissue degradation, and they do not explain whether “scarring,” “nerve pain” or “vaginal pain” are the type of adverse reactions polypropylene can trigger. Similarly, Plaintiffs allege that inserting the TVT-O through an area of the body that contains high levels of bacteria causes “immune reactions,” leading to “tissue breakdown” and other “adverse reactions.” *Id.* ¶ 68(b). Again, there are no allegations that Mrs. Johnson experienced immune reactions or tissue breakdown following her implantation surgery. *See, e.g., Baca*, 2020 WL 6450294, at \*4 (dismissing design defect claim where defect allegedly tended to cause “adverse immune response” because there were no allegations that plaintiff experienced such an injury).<sup>3</sup> Finally, with respect to the “propensity” of the TVT-O to “creep” or “elongate,” and the use of “non-medical grade material,” Plaintiffs do not enumerate any specific injuries that these purported defects tend to cause, let alone plausibly allege that Mrs. Johnson suffered from such injuries. *See id.* ¶¶ 68(d), (m).

Further, Plaintiffs fail to plausibly allege proximate cause with respect to the TVT-O’s “creation of a non-anatomic condition in the pelvis.” *See id.* ¶¶ 68(g). They allege that the “non-anatomic condition” leads to “chronic pain” and “functional disabilities,” *id.* ¶ 68(g), but they fail to explain *how* this characteristic caused the asserted injuries. *See Moore*, 217 F. Supp. 3d at 995; *Meredith v. Medtronic, Inc.*, Civ. No. 18-00127, 2019 WL 6330677, at \*4 (S.D. Iowa Oct. 25, 2019) (dismissing design defect claim in part because plaintiff failed to allege “how the tissue attachment properties of the [relevant mesh product] . . . caused his injuries”). While the Court does not expect

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<sup>3</sup> While “scarring,” “nerve pain,” and “vaginal pain,” *see* SAC ¶¶ 36–37, could overlap with some of the injuries that allegedly tend to result from the defects discussed herein, Plaintiffs bear the burden to plausibly allege that particular defects proximately caused the specific injuries Mrs. Johnson incurred. *See Baca*, 2020 WL 6450294, at \*4; *Bellew*, 2014 WL 6610685, at \*4.

plaintiffs to possess an intricate scientific understanding of a product, *see Moore*, 217 F. Supp. 3d at 996, neither may plaintiffs simply claim that a characteristic tends to cause the type of injuries they experienced without any support or explanation of the causal mechanism. *See Krulewich v. Covidien, LP*, 498 F. Supp. 3d 566, 576 (S.D.N.Y. 2020) (concluding allegations that the use of “polyester material” in hernia mesh “posed a substantial risk for severe [sic] inflammation” failed to adequately allege proximate cause without any further support or explanation). Without such explanation, the allegations are “conclusory,” and therefore, fail to state a claim. *Iqbal*, 556 U.S. at 678; *Krulevich*, 498 F. Supp. 3d at 576.

Accordingly, Plaintiffs state a design defect claim with respect to the following alleged defects: the transobturator procedure, the alleged “propensity” of the TVT-O to “contract or shrink” following implantation, the tendency of the mesh to degrade and fragment, the “pore size and stiffness” of the mesh, and the “inelasticity” of the mesh. SAC ¶¶ 35, 68(c), (e), (f), (h), (n). Plaintiffs are given leave to file a Second Amended Complaint containing a design defect claim that is premised on these defects. Plaintiffs are also given leave to amend to replead their allegations, if possible, concerning the remaining defects, for which the proposed SAC fails to state a design defect claim.<sup>4</sup>

#### **B. Strict Liability: Failure to Warn**

To state a claim for failure to warn—“known as an informational defect under Arizona law”—a plaintiff must plausibly allege “(1) that the defendant had a duty to warn, (2) that the missing warning made the product defective and unreasonably dangerous, (3) that the warnings were absent when the product left [the] defendant’s control, and (4) that the failure to warn caused [the] plaintiff’s injur[ies].” *Baca*, 2020 WL 6450294, at \*3 (citing *Sw. Pet Prods., Inc. v. Koch Indus., Inc.*, 273 F.

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<sup>4</sup> Defendants do not object to providing Plaintiffs one final opportunity to amend the complaint. *See* ECF No. 16 at 19.

Supp. 2d 1041, 1060 (D. Ariz. 2003); *Gosewisch v. Am. Honda Motor Co., Inc.*, 153 Ariz. 400, 403 (1987) (superseded on other grounds by A.R.S. § 12-2505)). Because this case involves a manufacturer’s sale of a “medical device . . . to a health-care provider for use by a patient, . . . the learned intermediary doctrine applies.” *Baca*, 2020 WL 6450294, at \*3. Under that doctrine, “a medical device manufacturer satisfies its duty to warn patients of the foreseeable risks involved with its products if it provides a complete, accurate, and appropriate warning to the patient’s health-care provider.” *Id.*

In Count Two, Plaintiffs do not specify any particular warnings that were allegedly absent from the TVT-O’s Instructions for Use (IFU). *See* SAC ¶¶ 84–86. Nevertheless, in their Reply, Plaintiffs direct the Court to certain defects they allege under their negligence claim in Count One, and they argue that the IFU failed to include warnings concerning these dangerous characteristics. *See* ECF No. 17 at 10. Accordingly, the Court will consider whether Plaintiffs are able to state a failure to warn claim based on these ostensibly omitted warnings.

Defendants first argue that the pleadings are inadequate because they do not “articulate the warnings that Ethicon . . . provided,” ECF No. 16 at 14, which is relevant to whether the proposed “warnings” Plaintiffs identify were in fact “absent.” *See Baca*, 2020 WL 6450294, at \*3. In their Reply, Plaintiffs urge the Court to take judicial notice of the warnings contained in the TVT-O IFU. ECF No. 17 at 9; TVT-O IFU, available at <http://hostedv1106.quosav1.com/qb/doc/0nnlfm86hbpkf33bt7pl38flvg> (last visited May 24, 2022). Because the IFU is publicly available and there is no risk that Defendants lack notice of its contents, the Court will take judicial notice thereof. *See Pension Ben. Guar. Corp.*, 998 F.2d at 1196–97; *Dye v. Covidien LP*, 470 F. Supp. 3d 1329, 1339 n.4 (S.D. Fla. 2020) (taking judicial notice of FDA-reviewed IFU accompanying hernia mesh product).

The IFU warns of several “Adverse Reactions” and “Undesirable Side Effects” that are

relevant here:

- As with any implant, a foreign body response will occur, the extent of which may differ. This response could result in extrusion, erosion, exposure, fistula formation and/or chronic inflammation, the severity of which is unpredictable, or other adverse reactions, which may be ongoing. . . .
- Infection following transvaginal implantation. As with all surgical procedures and the implantation of foreign bodies, there is a risk of infection and PROLENE Mesh may potentiate an existing infection. . . .
- [A]cute and chronic inflammation and ongoing risk of mesh extrusion, exposure, or erosion into the vagina or other structures or organs (such as bladder, urethra or rectum) which may be difficult to treat and result in consequent pain. . . .
- Pain - which may be severe and chronic. . . .
- Pain with intercourse (dyspareunia) . . . , which may be ongoing and may not resolve in some patients.
- Excessive contraction or shrinkage of the tissue surrounding the mesh, and vaginal scarring from causes including, but not limited to, chronic inflammation, mesh exposure.
- Neuromuscular problems, including acute and/or chronic pain in the groin, thigh, leg, pelvic and/or abdominal area, and leg weakness, may occur.

See TVT-O IFU at 6.

Considering these provisions, Plaintiffs fail to plausibly allege that several of the ostensibly missing warnings were in fact “absent” from the IFU. *Baca*, 2020 WL 6450294, at \*3. Plaintiffs allege that the TVT-O has “the propensity . . . to contract or shrink,” which “causes surrounding tissue to [become] inflamed, . . . fibrotic, and contract, harden and form painful scar tissue.” SAC ¶ 68(c); ECF No. 17 at 10. Yet, Plaintiffs fail to explain how this proposed warning differs materially from the warning in the IFU regarding “[e]xcessive contraction or shrinkage of the tissue surrounding the mesh,” as well as “vaginal scarring,” which may result from “chronic inflammation” and “mesh exposure.” See TVT-O IFU at 6. Plaintiffs also allege that the TVT-O is “inelastic[,],” which causes the product “to be improperly mated to the delicate and sensitive areas of the pelvis,” leading to “pain

upon normal daily activities . . . (e.g., intercourse, defecation, walking).” See SAC ¶ 68(e); ECF No. 17 at 10. But again, Plaintiffs fail to explain why this language was “absent” considering disclosures in the IFU that the TVT-O may cause “severe and chronic” “pain,” “[p]ain with intercourse (dyspareunia),” and “chronic pain in the groin, thigh, leg, pelvic and/or abdominal area.” See TVT-O IFU at 6.<sup>5</sup>

On the other hand, the proposed SAC states a failure to warn claim based on two sets of proposed warnings that do not appear in the IFU. Plaintiffs allege the IFU should have warned that the TVT-O “degrad[es] or fragment[s] over time, which causes a chronic inflammatory and fibrotic reaction and . . . chronic foreign body reactions, fibrotic bridging, . . . deformation, roping, rolling and curling of the mesh.” SAC ¶ 68(f), (h). They also contend the IFU should have warned that the “polypropylene material” in the TVT-O “is biologically incompatible with human tissue and promotes an immune response,” thereby causing “degradation of the pelvic tissue” and “severe adverse reactions.” SAC ¶¶ 68(a), 70; ECF No. 17 at 10.<sup>6</sup> The TVT-O IFU does not contain warnings related to the “immune response” that polypropylene material may cause when implanted in the pelvis or the risk that the mesh may “deform[], rop[e], roll[], and curl[],” leading to, *inter alia*, a

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<sup>5</sup> Although they do not emphasize these allegations in their Reply, Plaintiffs also allege under the negligence count that Defendants failed to provide adequate warnings regarding the propensity of the TVT-O “to erode, the rate and manner of erosion, the risk of chronic infections . . . , the risk of vaginal scarring, the risk of recurrent severe pelvic pain and other pain,” and “the need for corrective or revisionary surgery.” SAC ¶ 69. But Plaintiffs fail to explain how the IFU omitted these warnings given disclosures that the TVT-O poses the following risks: “mesh . . . erosion into the vagina or other structures or organs (such as bladder, urethra or rectum);” “[i]nfection following transvaginal implantation”; “vaginal scarring”; “chronic pain in the groin, thigh, leg, pelvic and/or abdominal area”; and the need for “[o]ne or more revision surgeries.” TVT-O IFU at 6.

<sup>6</sup> Plaintiffs similarly allege that implanting the TVT-O in an area with “high levels of bacteria that adhere to the mesh” may cause “immune reactions[,] . . . subsequent tissue breakdown[,] and [other] adverse reactions,” SAC ¶ 68(b), and the Court considers this to be part of the same warning as that related to the use of polypropylene mesh.

“fibrotic reaction” and “chronic foreign body reactions.” Nor do these risks appear in the FDA’s list of complications that are common to all SUI surgical procedures, with or without mesh. *See* ECF No. 16 at 13 n.2 (citing *Considerations about Surgical Mesh for SUI*, U.S. Food & Drug Admin., <https://www.fda.gov/medical-devices/urogynecologic-surgical-mesh-implants/considerations-about-surgical-mesh-sui>).

Plaintiffs also adequately plead proximate cause with respect to these warnings. Proximate cause requires plausible allegations that “the failure to warn caused [the] plaintiff’s injur[ies].” *Baca*, 2020 WL 6450294, at \*3. Where the learned intermediary doctrine applies, a plaintiff may plead proximate cause based on allegations that her treating physician would have conveyed a different recommendation, thereby altering the plaintiff’s decision to undergo treatment. *Dehart v. Johnson & Johnson*, Civ. No. 20-02493, 2021 WL 4427066, at \*5 (D. Ariz. Sept. 27, 2021) (denying motion to dismiss failure to warn claim and finding plaintiff adequately pleaded proximate cause where complaint “allege[d] that, had the additional warnings been provided, [the treating physician] would have conveyed them to [the plaintiff] and [the plaintiff] would have declined to consent to the surgery”).<sup>7</sup> Here, Plaintiffs allege that the omitted warnings “would have affected the treating physician’s use of the [TVT-O],” and that Mrs. Johnson in turn “would not have consented to the implantation [procedure].” *Id.* ¶ 81. The omitted warnings are also sufficiently connected to injuries that Mrs. Johnson allegedly sustained. *See Baca*, 2020 WL 6450294, at \*3. Plaintiffs allege that the

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<sup>7</sup> This proximate cause standard creates potentially puzzling implications insofar as a warning could cause a physician to alter her treatment recommendation, thereby preventing the plaintiff’s injuries, even if the warning is unrelated to a specific injury the plaintiff actually incurred. Nevertheless, in *Dehart*, the injuries specified in the allegedly omitted warnings were similar—though not identical—to the plaintiff’s injuries. *See* 2021 WL 4427066, at \*1, 4 n.5 (noting the plaintiff sustained injuries such as pelvic and rectal pain, dyspareunia, and worsening SUI, and the omitted warnings concerned, *inter alia*, chronic inflammation, permanent vaginal or pelvic scarring, and dyspareunia). The Court will therefore assume that proximate cause for purposes of failure to warn requires similarity—if not perfect alignment—between the plaintiff’s injuries and those specified in the omitted warnings.

tendency of the TVT-O to degrade and fragment may cause “a chronic inflammatory and fibrotic reaction,” which is consistent with the “vaginal pain” and “scarring” Mrs. Johnson experienced. SAC ¶¶ 37, 68(f), (h). Further, although Plaintiffs do not allege that Mrs. Johnson incurred the specific injuries polypropylene mesh purportedly causes—immune reactions and pelvic tissue degradation—there is a reasonable inference, as noted *supra*, that her vaginal pain and scarring could have resulted from these injuries, and the Court concludes that the injuries are sufficiently connected for purposes of the failure to warn claim. Accordingly, Plaintiffs have adequately alleged a failure to warn claim based on the foregoing proposed warnings.

### C. Negligence

Count One of the proposed SAC asserts a claim for negligence. Plaintiffs allege that Defendants were negligent with respect to the “design, manufacture, testing, inspection, processing, advertising, marketing, labeling, assembling, packaging, distribution, detailing, promotion and sale” of the TVT-O. SAC ¶ 66.

With respect to design defect and failure to warn, the Court concludes that Plaintiffs’ strict liability claims subsume—and render redundant—their negligence claims. Plaintiffs in Arizona may pursue products liability claims under strict liability or negligence theories. *See Granillo v. Johnson & Johnson*, Civ. No. 19-00529, 2020 WL 913300, at \*2 (D. Ariz. Feb. 12, 2020), *report and recommendation adopted*, 2020 WL 1285937 (D. Ariz. Mar. 18, 2020) (citing *Dart v. Wiebe Mfg., Inc.*, 147 Ariz. 242, 246–48 (1985)). No state court in Arizona has decided whether plaintiffs may proceed to trial under both negligence and strict liability theories, and courts in the District of Arizona are split on this issue. *Compare Granillo*, 2020 WL 913300, at \*2 (concluding plaintiffs may proceed under both theories), *with Dehart*, 2021 WL 4427066, at \*6–8 (concluding that the plaintiff’s strict liability claim subsumed his negligence claim). But the Court need not resolve this issue here because Plaintiffs do not advance any arguments in the Reply supporting independent negligent design or

failure to warn claims. ECF No. 17 at 11.<sup>8</sup> Accordingly, the negligent design and failure to warn claims are dismissed.

To the extent Plaintiffs assert a negligent manufacturing defect claim in the proposed SAC, they fail to state a plausible claim for relief. “In Arizona, the crux of a manufacturing defect claim is that the defective product differs from the manufacturer’s intended design or from other ostensibly identical units of the same product line.” *Baca*, 2020 WL 6450294, at \*2. The proposed SAC does not contain any such allegations. Indeed, a redline comparing the First and Second Amended Complaints shows that Plaintiffs removed the “manufacturing defect” claim that they had asserted in the First Amended Complaint. *See* ECF No. 15-3 at 15. Accordingly, the negligent manufacturing defect claim is dismissed.

Plaintiffs’ negligence claim in Count One is therefore dismissed.<sup>9</sup>

#### **D. Loss of Consortium**

“In Arizona, loss of consortium is a derivative claim such that” a plaintiff must prove “all elements of the underlying cause . . . before the claim can exist.” *Stengel v. Medtronic Inc.*, 306 F.R.D 230, 233 (D. Ariz. 2015) (quoting *Barnes v. Outlaw*, 192 Ariz. 283, 286 (1998)). Here,

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<sup>8</sup> The Reply states: “Plaintiffs admit that the facts provided under their Negligence cause of action are subsumed by their Arizona’s strict liability claims for Design Defect and Failure to Warn. Yet those claims should not be stricken (nor have Defendants asked them to be), but read as well-plead allegation[s] on which their Second and Third Causes of Actions rest.” ECF No. 17 at 11. It is therefore not clear whether Plaintiffs “admit” that the strict liability claims subsume the negligence claim, or only the *facts* alleged thereunder. Nevertheless, because Plaintiffs do not press an independent negligence claim on the merits, the Court construes the Reply as admitting that the strict liability claims subsume the negligence claim. The Court agrees with Plaintiffs that the facts alleged under their negligence claim (Count One)—including those related to design defects and omitted warnings—are incorporated into the strict liability claims (Counts Two and Three), as the Court’s analysis of the strict liability claims reflects.

<sup>9</sup> To the extent that the proposed SAC asserts a negligence claim under any other theory, such as inadequate “testing,” SAC ¶¶ 64, 67, Plaintiffs concede in their Reply that the strict liability claims for design defect and failure to warn subsume their entire negligence claim. *See* ECF No. 17 at 11.

Defendants contend that the Court should dismiss Mr. Johnson's claim for loss of consortium only on grounds that Plaintiffs fail to state an underlying products liability claim. ECF No. 16 at 19. However, because Plaintiffs have stated a claim for design defect and failure to warn, the claim for loss of consortium survives.

#### IV. CONCLUSION

For the reasons set forth above, Defendants' Motion to Dismiss the First Amended Complaint is **DENIED** as moot, and Plaintiffs' Motion for Leave to Amend is **GRANTED** in part and **DENIED** in part. Consistent with this Opinion, Plaintiffs may file a Second Amended Complaint that asserts strict liability claims for design defect and failure to warn, as well as a claim for loss of consortium. They are also given leave to replead their design defect claim, consistent with this Opinion, in an amended complaint, which they must file within twenty-one (21) days of the date of the accompanying Order. An appropriate form of Order is filed herewith.

Date: May 31, 2022

/s/ Freda L. Wolfson  
Hon. Freda L. Wolfson  
U.S. Chief District Judge